

NEI 07-06

The Nuclear Regulatory Process

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EXECUTIVE SUMMARY

The nuclear regulatory process provides a system for establishing requirements for nuclear power plants (including regulations, orders and licenses), for developing guidance to implement the requirements, for communicating with the licensees and the public, and for oversight and enforcement of the regulations. The process also establishes mechanisms for changes to operating licenses. Finally, the U.S. Nuclear Regulatory Commission has management and control processes for implementing and changing the process.

The nuclear regulatory process has evolved over the past several decades. Although no new operating licenses have been issued in more than a decade, the nation is looking at the strong possibility that many new nuclear power plants will be built, licensed and operated in the future. The industry recognizes that there is a significant number of experienced people who are knowledgeable of the development and evolution of the nuclear regulatory process who will soon retire. This creates a challenge for knowledge transfer for the new work force that will be responsible in the near future for the regulatory process.

This document presents a basic description of the nuclear regulatory process and its elements for operating nuclear power plants. It is intended to provide a foundation for maintaining a common understanding of the nuclear regulatory process, to refresh our knowledge of the nuclear regulatory process and to provide a foundation for transferring our knowledge to professionals entering the nuclear work force.

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THE NUCLEAR REGULATORY PROCESS

1 INTRODUCTION

This document presents a basic description of the nuclear regulatory process and its elements for operating nuclear power plants. It is intended to be an overview, which will provide the reader a firm grasp of the fundamental elements of the regulatory process and how it is intended to function. It does not attempt to address all aspects of the process; for example, it does not discuss the process of obtaining a construction permit, operating license, or the Part 52 processes, nor does it discuss the hearing process, or the fee recovery formula for the NRC budget. However, this document will provide the reader with a fundamental understanding of the basic structure and principles of the regulatory process, which will enable further study of the details.

The document presents an overall description of the legal authorities from which the U.S. Nuclear Regulatory Commission responsibilities were created and an overview of the technical basis for regulatory decision-making. In carrying out its basic responsibilities, the NRC imposes and communicates technical requirements and provides guidance for licensees in a variety of ways. Because there is a large variation in the formality of these communications, the authority of each element of the regulatory process must be thoroughly understood. This document categorizes the types of information in the regulatory arena into the basic areas listed below. Each is discussed in a section of this document. A focus of the discussion is on the proper establishment and revision of regulatory requirements.

This regulatory process description is organized, as much as possible, in a hierarchical manner, beginning with the legislative authority, through requirements, guidance, communications, oversight and enforcement, the licensee's role, and finally administrative management and control of the process. Refer to Figure 1.1, which corresponds to the sections of the paper.

Section 2, The Role of the Nuclear Regulatory Commission, describes the organization and functions of the NRC, its legal bases (including AEA, the Atomic Energy Act), and its relationships with other entities, including the federal legislative, executive and judicial branches, states, licensees and the general public.

Section 3, NRC Requirements, discusses binding requirements on licensees. The section describes regulations (and how they are developed), orders and licenses and plant technical specifications.

Section 4, NRC Regulatory Guidance and Staff Interpretations, discusses detailed technical guidance that provides acceptable methods of meeting the requirements in the regulations. Guidance documents and staff interpretations do not establish or revise requirements; rather, they represent approaches that are acceptable to the NRC staff for meeting the requirements. Alternative approaches may be used if determined to be acceptable to the NRC.

Section 5, NRC Generic Communications, describes the various means by which the NRC communicates to all licensees. They consist of bulletins, generic letters, regulatory information summaries and information notices. These communications are used to request information from, or provide information to, licensees, and may not be used to implement new requirements.

Section 6, NRC Reactor Oversight and Enforcement Process, describes how the NRC inspects licensees to assure compliance with the regulations; how it determines the significance of regulatory violations; how it assesses the overall performance of licensees and when additional inspection oversight is necessary; and the enforcement process.

Section 7, The Licensee Role in the Regulatory Process. An NRC licensee has primary responsibility for safe operation of the nuclear facility. Once the NRC issues an operating license, a plant owner must ensure compliance with the license. Since a plant's design and operation are not static, certain changes are necessary over the course of the plant's life. Licensees must follow NRC processes to justify and make those changes.

Section 8, NRC Management and Control of the Regulatory Process, discusses the formal mechanisms that exist to ensure the NRC acts in a legal, structured and disciplined manner in its licensing and oversight of nuclear power plants. These management and control mechanisms include statutes and regulations, commission direction to the staff, and specific procedures to ensure that the NRC achieves its legislative mandate and provides due process to its licensees.

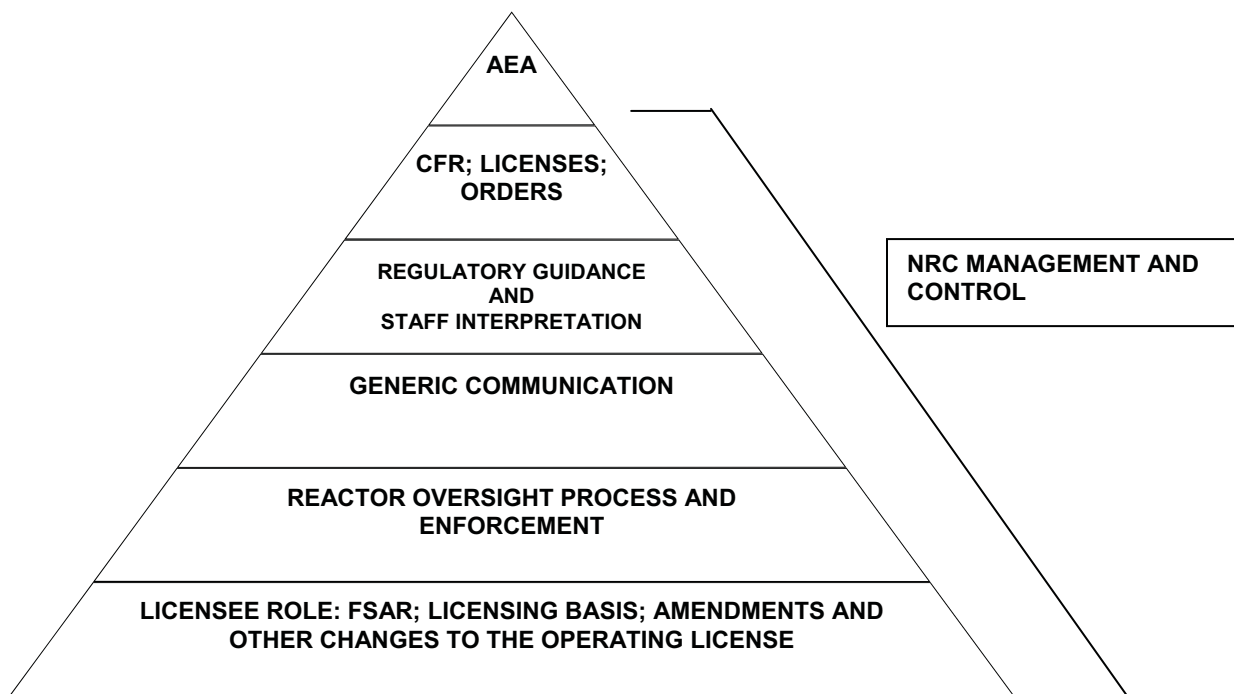


Figure 1.1

2 THE ROLE OF THE NUCLEAR REGULATORY COMMISSION

2.1 ORGANIZATION AND FUNCTIONS

The U.S. Nuclear Regulatory Commission is the federal agency responsible for licensing and regulating nuclear facilities and materials and for conducting research in support of the licensing and regulatory process. The NRC's responsibilities include protecting public health and safety, protecting the environment, protecting and safeguarding nuclear materials and nuclear power plants in the interest of national security, and assuring conformity with antitrust laws. To carry out its mission of regulating licensed nuclear material, the NRC functions by: standards setting and rulemaking; technical reviews and studies; conduct of public hearings; issuance of authorizations, permits and licenses; inspection, investigation and enforcement; evaluation of operating experience; and confirmatory research.

As differentiated from the agency itself (referred to as the NRC), the *commission* is composed of five individuals appointed by the president and confirmed by the United States Senate. One commissioner is designated by the president as chairman and acts as the principal executive officer and official spokesman of the commission. The commission works as a collegial body to formulate policies, develop regulations governing nuclear reactor (and nuclear material) safety, issue orders to licensees, and adjudicate legal matters. The NRC's executive director for operations (EDO) carries out the policies and decisions of the commission and directs the activities of the NRC program offices.

2.2 LEGAL BASES FOR NRC AUTHORITY

The process of implementing the NRC's mandate has been an evolutionary one. The Atomic Energy Act of 1946 created the Atomic Energy Commission (AEC) and gave the AEC authority over nuclear material. At that time, Congress recognized the national interest in regulating nuclear material but the private (non-military) use of nuclear material was largely non-existent.

In the Atomic Energy Act of 1954 (AEA), Congress gave the AEC broad powers to develop, use and control the private use of nuclear facilities and nuclear material. The statute required that the development, use and control of atomic energy be directed so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise. It required that civilian uses of nuclear materials and nuclear facilities (including, but not limited to, power reactors) be licensed, and authorized the AEC to govern the use of atomic energy as the commission may deem necessary or desirable in order to protect health and safety and minimize danger to life or property. Under the AEA, the AEC both promoted and regulated the civilian uses of nuclear materials and nuclear facilities. The commission also retained responsibility for the military application of nuclear materials and development of weapons.

The Energy Reorganization Act of 1974 (ERA) abolished the AEC and transferred its licensing, inspection, and related regulatory functions, and control over the civilian use of nuclear facilities and material, to the newly formed NRC. AEC jurisdiction over the military and promotional uses of atomic energy was transferred to the Energy Research and Development Agency and later to the U.S. Department of Energy. Thus, with the enactment of the ERA, the agency was no longer charged to promote the industry that it regulated.

The AEA remains the primary authority for the NRC's implementing regulations (set forth in Title 10 of the Code of Federal Regulations) and NRC activities. The AEA specified the agency's organization and the nuclear materials and nuclear facilities that the NRC is to license and regulate. Further, it established the processes for issuing NRC licenses (including public hearings), inspecting facilities, promulgating regulations and imposing enforcement sanctions.

Other statutes that govern or significantly affect the activities of the NRC include:

- The Administrative Procedure Act
- The Low-Level Radioactive Waste Policy Amendments Act of 1985
- The National Environmental Policy Act
- The Nuclear Non-Proliferation Act of 1978
- The Nuclear Waste Policy Act of 1982, as amended
- The Uranium Mill Tailings Radiation Control Act of 1978
- The Energy Policy Act of 2005

A detailed discussion of these statutes is beyond the scope of this paper; however, the importance of the Administrative Procedure Act to the regulatory process will be discussed in several sections. The NRC's Web site provides a brief summary of each of these federal laws as they affect the functioning of the NRC.

2.3 NRC'S RELATIONSHIPS WITH OTHER ENTITIES

The NRC is an independent federal regulatory agency. It is not part of the executive branch and answers to Congress rather than the president. There are currently several congressional committees and subcommittees with oversight and authorization jurisdiction over NRC activities. The president nominates NRC commissioners (with Senate confirmation) and selects the chairman. The Office of Management and Budget (OMB) provides budgetary oversight. The Environmental Protection Agency has responsibility for radiation standards, and also standards for license termination (decommissioning), and the storage and disposal of used nuclear fuel, specifically, Yucca Mountain. The NRC also interacts with other federal agencies, including the Department of Transportation, the Occupational Safety and Health Administration, the Federal Emergency Management Agency, and the Department of Homeland Security.

Final NRC actions are subject to judicial review by the federal courts, whose decisions may require the agency to modify its regulations or other programs. The NRC also interacts with stakeholders outside of the federal government, including the nuclear industry, the general public, and special interest groups that may support or oppose the use of nuclear energy.

The NRC also interacts with the states. The AEA authorizes a limited degree of state participation, on a cooperative basis, in the uses of nuclear material and the oversight of nuclear power reactors through inspections or other functions; however, the NRC retains ultimate, exclusive authority to regulate the radiological safety and security aspects of facility construction and operation, the importing or exporting of nuclear licensed materials or facilities, spent fuel storage and disposal of licensed material. The NRC may “discontinue” or, in effect, cede to a state its regulatory authority over source, byproduct and special nuclear material below a critical mass, under the Agreement States Program. States that have assumed this authority are commonly referred to as “Agreement States.” Currently, 34 of the 50 states administer Agreement State programs.

Another important role of state and local governments is offsite emergency planning. State and local government officials have the overall responsibility of deciding and implementing the appropriate protective actions for the public during a nuclear power plant radiological emergency. They are responsible for notifying the public to take protective actions. State and local officials base their decisions on the protective action recommendations by the nuclear power plant operator and their own radiological or health organization. The NRC provides advice, guidance, and support to the state and local government officials. Neither the nuclear power plant operator nor the NRC can order the public to take protective actions.

The NRC does not have exclusive jurisdiction over all uses of nuclear material. The NRC does not license or regulate most uses of nuclear material by DOE or the Department of Defense; DOE’s production of nuclear material for military applications; or nuclear reactors used for defense (e.g., nuclear powered warships). While the NRC has jurisdiction over sources, it does not have jurisdiction over other discrete naturally occurring radioactive material (NORM), such as radon, which is regulated by the states.

3 NRC REQUIREMENTS

3.1 BINDING REQUIREMENTS: REGULATIONS, ORDERS AND LICENSES

The NRC implements its statutory mandate in several ways. The AEA authorizes the agency to impose binding legal requirements through rules, regulations and orders. The NRC also issues licenses, including licenses to manufacture, produce, transfer, acquire, possess, use, import or export licensed material, and licenses for utilization and production facilities. NRC licensees must comply with the terms of their licenses, unless they are specifically not required to comply (e.g., through the granting of formal exemptions or relief requests). Additionally, the NRC verifies that plants are being operated in accordance with the agency's regulations through its inspection and enforcement processes, addressed in Section 6.

To establish legally binding requirements, the NRC must promulgate those requirements in accordance with the applicable procedures specified in the Administrative Procedure Act (APA). NRC requirements established by rulemaking or by adjudication in accordance with the APA are the only requirements that are directly enforceable. These requirements (NRC regulations, orders and licenses) must be met by NRC applicants and licensees to maintain compliance.

A *rule* is an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. (An NRC regulation is the same as an NRC rule.) An *order* is a final disposition, whether affirmative, negative, injunctive or declaratory in form, of an agency in a matter other than rulemaking but including licensing. At the end of the licensing process, the NRC may issue a *license*: an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission.

The APA governs each of these processes. Certain procedural and due process protections apply to each of these forms of agency actions, including an opportunity for affected persons to participate through submission of written data, comments or arguments. The agency is also required to make its decisions publicly available, along with a general statement of basis and purpose. In general, the decision whether to use rulemaking or adjudication (orders) to address a regulatory problem or issue is within the discretion of the agency. The NRC uses both of these processes to impose new requirements on licensees, individuals, and vendors where applicable.

3.2 THE RULEMAKING PROCESS

In addition to establishing legally binding obligations by adjudication (orders), the NRC also imposes enforceable obligations by rules (regulations). NRC rules are developed by an open process referred to as "rulemaking," which is conducted in conformance with APA procedures. The need for a new or amended NRC regulation can arise from various sources, including: (1) a new statute requiring new regulatory requirements; (2) a commission directive or NRC staff initiative indicating a need for further regulation to resolve a safety, safeguards or environmental problem; or (3) commission receipt of a petition for rulemaking from an interested person.

To understand the agency's internal rulemaking process in any detail, one must consult NRC guidance documents, which are provided in NRC Management Directive 6.3, *The Rulemaking Process*. Procedures and guidance for rulemaking development are also provided in LIC-300, *Rulemaking Procedures*.

Before it begins the formal rulemaking, the NRC initiates an internal vetting process for the issue(s) in question to ensure that any subsequent rulemaking activities are conducted in an orderly, systematic manner with due attention to schedule and NRC resources. As part of this preparation for rulemaking, the agency may consider various proposed solutions (both regulatory and non-regulatory) to the issue(s) in question. The NRC also considers possible technical bases for a new rule, the extent to which there is NRC policy support for the rule and underlying technical basis, the cost-benefit analysis associated with changing existing NRC requirements, the anticipated effect on NRC licensees and on the agency itself, safety benefits, reductions in regulatory burden and other factors.

If a rulemaking action is approved, a draft rulemaking plan is typically prepared, along with a schedule of activities. At this stage, the agency considers the need for review of the rulemaking package by the Advisory Committee on Reactor Safeguards, the Advisory Committee on Nuclear Waste, and the Committee to Review Generic Requirements; whether an environmental assessment (EA) or environmental impact statement (EIS) should be prepared; and the priority of the rulemaking, among other factors. The draft rulemaking plan package goes through an internal review and concurrence process.

If the rulemaking moves forward, the NRC continues to follow detailed internal procedures intended to ensure that the agency fully considers the impacts of the proposed rule. A proposed rule package is prepared. This package includes the *Federal Register* notice (containing the text of the proposed rule and any supplementary information). It also includes supporting documents, such as the regulatory analysis (which examines the economic impact of alternatives considered in developing the proposed rule), the EA or EIS addressing potential environmental impacts, the backfit analysis, a clearance request to the OMB (in connection with any information collection requirements subject to the Paperwork Reduction Act), congressional letters, a press release and regulatory guidance. If the proposed rule is to go to the commission, a commission paper transmitting the rulemaking from the executive director for operations (EDO) to the commission is prepared.

After completion of the internal concurrence review, the commission votes on the proposed rule package and sends the EDO a Staff Requirements Memorandum (SRM) containing the results of its vote and commission direction (if any) regarding any changes to be made to the rulemaking package. NRC obtains OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act. After any necessary changes are made, the proposed rule package is published in the *Federal Register*.

During the course of a rulemaking, NRC staff may elect to conduct one or more public meetings or workshops to obtain public input. Meeting topics may range from a specific regulatory issue or a portion of the regulations that is a candidate for amendment, to specific draft rule language under consideration at either the proposed or final rule stage. In most cases, the NRC makes

publicly available draft rulemaking language prior to the issuance of a proposed rule. This information sharing is intended to facilitate stakeholder involvement and allow resolution of associated issues prior to publication of the proposed rule.

After the proposed rule is published and public comments on the rule have been submitted, the NRC considers those comments and decides how to resolve them in the final rule. The NRC staff develops a final rulemaking package, including the supporting documents and the disposition of the public comments. After internal review and concurrence, the NRC publishes a final rule in the *Federal Register*. The rule becomes effective on whatever effective date is set forth in the final rule. NRC regulations are codified in Title 10 of the Code of Federal Regulations (CFR) after they are promulgated.

3.2.1. APA Statutory Requirements Governing NRC Rulemaking

The open rulemaking process used by the NRC involves public notice and comment procedures. An agency must first (1) publish a general notice in the *Federal Register*, (2) give interested persons an opportunity to participate in the rulemaking through submission of written data, views or arguments, and (3) incorporate a concise general statement of the rule's basis and purpose. The *Federal Register* notice must include a statement of the time, place and nature of the public rulemaking proceeding and the legal authority under which the rule is proposed. The notice must also describe either the terms or substance of the proposed rule or a description of the subjects and issues involved. In practice, the text of the proposed and final rule is published.

When an advanced notice of proposed rulemaking, a proposed rule, a final rule or a direct final rule is published in the *Federal Register*, Supplementary Information (formerly designated the Statements of Consideration) is included, which satisfies APA requirements that the rulemaking notice provide a concise general statement of the basis and purpose of the proposed rule and the public comments thereon. The Supplementary Information section in NRC rulemaking notices typically contains useful background information, the regulatory history of the rule, an explanation of the rule's underlying intent and basis and, for final rules, a discussion of how the NRC staff addressed public comments. Often this section sets forth the NRC's view on how the rule language should be interpreted. In sum, the Supplementary Information explains the NRC staff's rationale for the regulation in sufficient detail to provide the courts with a factual and reasoned explanation to serve as a basis for judicial review. Commission language in the Supplementary Information accompanying an NRC rule provides insights regarding the commission's intent in the particular rulemaking.

3.3 ORDERS

NRC requirements established by adjudication include orders of the commission, NRC staff confirmatory orders, and Atomic Safety and Licensing Board orders. This category also includes operating licenses, since they are a form of order issued by adjudication. License requirements include license conditions and technical specifications. (Note that technical specifications are incorporated into the license under 10 CFR 50.36(b).)

The NRC imposes binding regulatory requirements via order when the NRC staff finds that a certain action on the part of one or more licensees is necessary to protect the health and safety of

the public or the common defense and security. An order is a written NRC directive to modify, suspend or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper. Orders also may be issued in lieu of, or in addition to, civil penalties for Severity Level I, II or III violations.

Orders can be considered either compliance orders or safety orders. *Compliance orders* are issued to mandate compliance or additional actions in light of a noncompliance. Typically, the NRC regional office or the NRC program office responsible for the inspection area or activity initiates compliance orders. *Safety orders*, typically imposing new requirements beyond the current existing regulatory framework, may be imposed in unusual circumstances to provide reasonable assurance of public health and safety. In such circumstances, the NRC Office of Nuclear Reactor Regulation (NRR) may issue a modification order to impose additional requirements; to modify, suspend or revoke the license; or take other action that is incorporated as a condition of the operating license. Procedures and guidance for development of safety orders are found in NRR Office Instruction LIC-106, *Issuance of Safety Orders*.

3.4 NRC LICENSES AND TECHNICAL SPECIFICATIONS

The NRC is authorized to license and to regulate nuclear facilities (e.g. commercial nuclear power reactors, research reactors, uranium enrichment facilities, fuel fabrication facilities, spent nuclear fuel storage facilities, high-level radioactive waste disposal facilities) and nuclear materials (radioactive source material, special nuclear material and byproduct material).

A comprehensive discussion of the NRC licensing process (which applies to facility licenses and materials licenses) is beyond the scope of this paper. In brief, NRC regulations govern the process of applying for a license, amending a license after it is issued, extending a license and decommissioning a license for a nuclear facility. Each NRC license is issued for a specific period of time; for example, reactor operating licenses (OLs) are issued for a period of 40 years. The issuance and amendment of reactor operating licenses is governed by NRC regulations in 10 CFR Part 50; the renewal of reactor operating licenses is governed by 10 CFR Part 54. More recently, NRC has promulgated regulations in 10 CFR Part 52 that apply to the issuance of Early Site Permits, Design Certifications, and Combined Operating Licenses (COLs).

The AEA and NRC regulations require that nuclear power plant OL applications include technical specifications (tech specs) relating to the amount, kind, and source of special nuclear material required, the place of usage, the facility's characteristics, and other information, as well as the basis for each tech spec proposed. When the NRC issues a reactor operating license, the OL typically contains tech specs that define mandatory operating limits and other requirements and actions that must be taken to ensure protection of public health and safety and the environment. Section 10 CFR 50.36 addresses tech spec content, which must include: (1) safety limits, limiting safety system settings and limiting control settings; (2) limiting conditions for operation; (3) surveillance requirements; (4) design features; and (5) administrative controls. The AEA specifies that tech specs are a part of the license. Prior NRC approval is required to deviate from tech spec requirements. The licensee's role in requesting changes to the operating license, the technical specifications and the design basis and current licensing basis are discussed in Section 7.

4 NRC REGULATORY GUIDANCE AND STAFF INTERPRETATIONS

4.1 OVERVIEW

The NRC routinely interprets, or otherwise clarifies, the agency's regulatory requirements in either a generic guidance document (e.g., NUREGs, regulatory guides, and branch technical positions) or in case-specific actions (e.g., safety evaluations, inspection reports, enforcement actions). It is important to note that staff interpretations are informal and non-binding on the commission. Except as specifically authorized by the commission, no interpretation of the meaning of the regulations by any officer or employee of the commission other than the general counsel will be recognized as legally binding.

NRC guidance is used to communicate approaches acceptable to the NRC staff for meeting NRC requirements. As opposed to NRC regulations, orders and licenses, the NRC's regulatory guidance, staff interpretations, and information documents do not (in and of themselves) have the force of legally binding *requirements*. NRC staff interpretations and guidance are not issued in accordance with the APA and (unless they are imposed in an order) do not constitute legal requirements. The enforceability of NRC staff guidance and interpretations flows from the underlying regulatory obligations, not from the NRC guidance document itself. Because NRC guidance documents are not the equivalent of NRC rules, the staff interpretations in these documents may be subject to challenge. Methods and solutions different from those set out in the NRC guidance documents may be acceptable to the NRC based upon plant-specific review.

4.2 STANDARD REVIEW PLANS

The NRC has developed Standard Review Plans (SRPs) for reviewing various types of licensee submittals to ensure consistency of NRC staff reviews and to ensure the technical adequacy of the licensee's submittal. According to NRC regulations, the SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant/licensee meets the commission's regulations. The SRP contains *guidance for NRC staff reviewers* for performing safety reviews for applications to construct or operate nuclear power plants, or to obtain operating license amendments. SRPs address: (1) responsibilities of NRC staff reviewers; (2) matters that are reviewed; (3) the commission's regulations and acceptance criteria necessary for the review; (4) how the review is accomplished; (5) the conclusions that are appropriate; and (6) implementation requirements. SRPs also serve to make information about regulatory matters widely available and to improve communication and understanding of the NRC staff review process by stakeholders. Of particular interest to reactor licensees is NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants*.

The NRC recognizes that: "The SRP is not a substitute for the regulations, and compliance is not a requirement." However, NRC regulations require power reactor operating license applicants to evaluate their facility against the SRP in effect six months prior to the docket date of the license application. This evaluation must include "an identification and description of all differences in design features, analytical techniques, and procedural measures" proposed for a new facility and

those corresponding features in the SRP. Where a difference exists, the evaluation must discuss “how the alternative [to the SRP acceptance criteria] proposed provides an acceptable method of complying” with the NRC's regulations underlying the acceptance criteria.

The SRP is part of a continuing regulatory standards development activity that not only documents current methods of review, but also provides a base for modification of the review process in the future. It is updated periodically as the need arises. A major project is currently underway to update the SRP to support new plant applications. Procedures and guidance for development of SRP sections are provided in NRR Office Instruction LIC-200, *Standard Review Plan (SRP) Process*.

4.3 BRANCH TECHNICAL POSITIONS

Branch technical positions (BTPs) are guidelines intended to supplement the acceptance criteria in NRC regulations and regulatory guides and are provided as appendices to the SRP. As technical issues or questions of interpretation arise in the detailed reviews of plant designs, the staff must determine an acceptable resolution for each case to complete its review of a particular application. Where the same technical issue or question of interpretation recurs, the staff's determination on the point at issue is formalized in a BTP. Thus BTPs are primarily instructions to NRC staff reviewers that outline an acceptable approach to, or position on, a previously considered technical safety or design matter, and that are intended to ensure a uniform treatment of the issue by staff reviewers. BTPs can contain or reference properly established regulatory requirements, but *cannot be used* to establish new regulatory requirements or revise existing ones.

4.4 REVIEW STANDARDS

As an adjunct to the comprehensive SRP (NUREG-0800), the NRC has also developed several review standards. Review standards were created in response to an Advisory Committee on Reactor Safeguards recommendation concerning the need for an SRP to enhance the consistency, quality, and completeness of the NRC staff's review of complex licensing actions with which the NRC has not yet had much experience. Currently, there are two review standards dealing with power uprate applications and early site permit applications. In an effort to standardize NRC staff reviews of complex licensing actions, the review standards are intended to provide: (1) a clear definition of the review standards and scope, (2) references to existing review criteria (i.e., applicable SRP sections, BTPs, office instructions, information notices, generic letters, bulletins, NUREGs, industry standards, etc.), and (3) template safety evaluations. As with other staff interpretations, the guidance contained in review standards does not establish regulatory requirements.

4.5 REGULATORY GUIDES

Regulatory guides (RGs) are typically issued to define approaches acceptable to the NRC that licensees may take to comply with regulatory requirements. RGs may also provide sufficient information to help the NRC staff perform its function. RGs provide guidance for preparing a license application. They also describe acceptable methods for implementing NRC regulations, techniques used by the NRC staff in evaluating specific problems or postulated accidents, and

data needed by the staff in its review of license applications and amendments. A licensee may choose to docket a commitment to a regulatory guide when it applies for or modifies its license.

Regulatory guides are not a substitute for regulation, and do not establish regulatory requirements. In most cases, methods outlined in the RG are not the only method acceptable to the NRC staff for implementing NRC regulations; solutions different from those in the RG may be acceptable if a basis that is equivalent in the level of protection or effectiveness is demonstrated. A licensee is free to rely on the RG approach, or to take alternative approaches if it can show that the underlying legal requirements are being met. RGs also may endorse, or endorse with exceptions, industry standards from organizations such as the American Society of Mechanical Engineers, the Institute of Electrical and Electronics Engineers, the American Nuclear Society, the Electric Power Research Institute and the Nuclear Energy Institute.

Three regulatory guides are cited in 10 CFR 50.55a, Codes and Standards. This, in effect, establishes these guidance documents as regulatory requirements.

4.6 NUREGs

The NRC NUREG series includes NRC staff and NRC contractor reports on unclassified scientific, technical and administrative information dealing with licensing and regulation of nuclear facilities and materials. These publications present information that may be used to support regulatory decisions, guidance for meeting regulations, results of task force investigations of specific topics or incidents, results of NRC or contractor research programs, resolution of generic safety issues, analyses of certain regulatory programs, proceedings of conferences and workshops, etc. Reports of this type are identified by an alphanumeric designator in the NUREG series (NUREG for a report, NUREG/BR for a brochure, NUREG/CR for a contractor report, NUREG/CP for conference proceedings). Some NUREGs are used to publish Standard Review Plans (for example, NUREG-1800, *Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants*).

NUREG documents do not contain legally binding regulatory requirements, although the NRC staff may incorporate part, or all, of the information in them into the regulations using the formal rulemaking process.

4.7 INTERIM STAFF GUIDANCE

Interim Staff Guidance (ISG) documents are issued by an NRC office to clarify an aspect of the SRP or to address issues not discussed in an SRP. As suggested by its name, an ISG document serves as a placeholder guidance document until it is incorporated into the next revision of the applicable (permanent) guidance document. ISGs are currently being used by: Division of Spent Fuel Storage and Transportation; License Renewal; Fuel Cycle Safety and Safeguards; and High Level Waste Repository Safety. If the NRC staff determines that development of an ISG is appropriate, it issues a *Federal Register* notice requesting comments on the proposed ISG. At any step during the process, a proposed ISG can be modified or determined to be unnecessary. In the latter situation, the NRC staff will document the closure of the issue in a letter to the interested stakeholders and a *Federal Register* notice. The guidance contained in ISGs does not establish regulatory requirements.

5 NRC GENERIC COMMUNICATIONS

Generic communications address generic concerns that evolve from nuclear reactor operating experience and regulatory initiatives that have broad applicability. LIC-503, Revision 2, *Generic Communications Affecting Nuclear Reactor Licensees*, provides guidance and procedures for generic issue preparation, distribution, follow-up, and closeout. Under the current Generic Communication Program, the NRC can issue bulletins, generic letters (GLs), regulatory issue summaries (RISs), and information notices (INs). Each of these regulatory guidance documents is discussed below. None of these generic communications may be used to impose new requirements.

Historically, the industry has commented that the NRC's generic communications were imprecisely understood. As a result, the NRC revised its Generic Communication Program in an effort to: (1) distinguish the role of bulletins and generic letters and (2) clarify that bulletins and generic communications would no longer be used to convey information. RISs, in particular, are now used to clarify the interpretation of agency regulations.

5.1 BULLETINS

An NRC bulletin requests information, requests specific action and requires a written response from the addressees regarding matters of safety, safeguards or environmental significance, in accordance with 10 CFR 50.54(f). The NRC issues bulletins to address urgent and significant issues with generic applicability. A bulletin cannot establish legally binding regulatory requirements. A bulletin is subject to Committee to Review Generic Requirements (CRGR) review. (CRGR will be discussed in Section 8.) The commission has requested that it be kept informed of the NRC staff's intention to issue a bulletin.

Recipients may be asked to respond to a bulletin by taking compensatory action commensurate with the urgency of the issue being addressed, to provide requested information, and to perform and submit analyses by a specified time. A bulletin may not request continuing or long-term actions. A bulletin may *request* new or revised licensee commitments based on analyses performed and licensee-proposed corrective actions; however, a bulletin may not require licensee commitments.

5.2 GENERIC LETTERS

The NRC uses generic letters (GL) to address emergent or routine generic technical issues, where the NRC staff has concluded that a generic communication is an appropriate means to effect resolution. Generic letters can also be used for a risk-significant compliance matter that the NRC staff has concluded should be brought to the attention of the nuclear industry without extensive prior interaction. A GL may request information and/or specified action by the recipient regarding matters of safety, safeguards or environmental significance. GL recipients may be asked to report the completion of actions requested by the NRC in their docketed response to the GL. A GL may request that recipients perform analyses and submit them for staff review, provide descriptions of proposed corrective actions for staff review, and take corrective actions by a specified time.

A GL may *request* new or revised licensee commitments based on analyses performed and proposed corrective actions. It may not *require* licensee commitments or establish regulatory requirements. The NRC staff may exercise discretion in preparing information requests by not always requiring a written response in accordance with 10 CFR 50.54(f). A generic letter is subject to CRGR review and the commission has requested that it be informed of the NRC staff's intention to issue a generic letter. Proposed generic letters are published in draft form in the *Federal Register* for public comment.

5.3 INFORMATION REQUESTS PURSUANT TO 10 CFR 50.54(F)

Typically, requests for information identified in bulletins and generic letters cite the provisions of 10 CFR 50.54(f). The NRC may request information needed to (1) review situations that may involve serious questions regarding plant safety (e.g., unreviewed safety questions), and (2) determine the need to modify, suspend, or revoke an NRC license. Section 10 CFR 50.54(f) provides that: "Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information."

NRC Management Directive 8.4, *NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants*, provides guidance for NRC staff implementation of 10 CFR 50.109 and 10 CFR 50.54(f). In addition, procedures and guidance for the use of 10 CFR 50.54(f) are provided in NRR Office Instruction LIC-202, *Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests*.

5.4 REGULATORY INFORMATION SUMMARIES

Regulatory information summaries (RISs) are informational documents that the NRC uses to communicate with the nuclear industry on a broad spectrum of matters with generic applicability. The NRC has used RISs to:

- Document NRC endorsement of industry-developed issue resolutions, or industry guidance on technical or regulatory matters.
- Provide the status of staff-industry interaction on certain matters.
- Request licensees' voluntary participation in NRC-sponsored pilot programs.
- Inform licensees of opportunities for regulatory relief.
- Announce NRC staff technical/policy positions, particularly on matters not previously communicated to the nuclear industry or not fully understood.
- Provide guidance on regulatory matters, such as the scope/detail of information that should be provided in licensing applications to facilitate staff review.
- Announce the availability of regulatory documents (topical reports, NUREGs, documents discussing the closeout of generic safety issues).
- Request voluntary submittal of information to assist in the regulatory process.
- Announce changes in agency practice that could impact licensees.

The NRC now uses a RIS to address all matters previously reserved for NRC administrative letters. A RIS does not involve a request for action or information unless the request is “strictly voluntary.” A draft RIS may be published for public comment in the *Federal Register* in order to benefit from stakeholder comment prior to issuance. Although a RIS is not typically subject to CRGR review, the NRR staff may, in its discretion, refer a RIS to the CRGR for review.

5.5 NRC INFORMATION NOTICES

The NRC uses information notices (INs) to inform the nuclear industry of recently identified, significant operating experience that may have generic applicability. While an IN cannot establish or imply new regulatory requirements or new interpretations, NRC licensees are expected to review the information for applicability to their facilities or operations and consider actions, as appropriate, to avoid similar problems. An information notice is not subject to CRGR review and is not published in draft form in the *Federal Register* for public comment.

6 NRC REACTOR OVERSIGHT AND ENFORCEMENT PROCESS

It is the policy of the NRC to provide oversight of nuclear power plant activities to verify that the plants are being operated in accordance with NRC rules and regulations. The regulated licensee is ultimately responsible for the safety of its activities and the safeguarding of nuclear facilities and materials used in its operation. The NRC ensures that the licensee adequately discharges this ultimate responsibility through an inspection and enforcement program. The inspection program uses a sampling approach to provide reasonable assurance of protection of public health and safety.

6.1 INSPECTION AND ENFORCEMENT AUTHORITY

The NRC's inspection and enforcement authority derives from the AEA and the Energy Reorganization Act of 1974. NRC regulations implementing this statutory authority are set forth in 10 CFR Part 2, subpart B. In addition to conducting inspections and investigations and issuing orders, the NRC may take various forms of enforcement action, up to and including modifying, suspending or revoking licenses (e.g., for material false statements, for a licensee's failure to build or operate a facility in accordance with its license, for violations of NRC regulations, and for conditions that would have warranted refusal of an original license). The NRC may also impose civil penalties and, in some cases, criminal penalties (monetary fines or imprisonment). Alleged or suspected criminal violations are referred to the U.S. Department of Justice.

6.2 REACTOR OVERSIGHT PROCESS

The NRC's Reactor Oversight Process (ROP), implemented in April 2000, integrates inspection, enforcement and assessment of nuclear power plants in a risk-informed, performance-based system to ensure the appropriate level of NRC oversight of licensees. The process is designed to focus on those plant systems, structures, components and activities that are most risk significant. The ROP provides a "closed loop" oversight process: The level of oversight increases as licensee performance declines, and decreases to a minimum baseline of oversight as performance improves. NRC conducts a minimum baseline inspection of about 2000 hours per reactor per year. These inspections are conducted by the resident inspectors (there are at least two resident inspectors at each plant site full time) and specialists from the regional or national headquarters. Inspection findings and performance indicators are used to assess licensee safety performance. Licensee safety performance determines the level of NRC oversight, which is increased above a minimum baseline of inspection as plant performance declines, and decreases back to the baseline as performance improves. Management Directive 8.13, *Reactor Oversight Process*, describes the process.

The NRC's regulatory framework for reactor oversight (shown in Figure 6.1) is a risk-informed, tiered approach to ensuring plant safety. It includes three strategic performance areas: reactor safety, radiation safety and safeguards. Within each strategic performance area are cornerstones that reflect the essential safety aspects of facility operation. The cornerstones are: (1) initiating events, (2) mitigating systems, (3) integrity of barriers to release of radioactivity, (4) emergency preparedness, (5) occupational radiation safety, (6) public radiation safety, and (7) physical

protection. Satisfactory licensee performance in the cornerstones provides reasonable assurance that the facility is operating safely and that the NRC’s safety mission is being accomplished.

In addition to the cornerstones, the ROP features three cross-cutting areas that can affect each of the cornerstones. The cross-cutting areas include:

- Human performance
- Safety-conscious work environment (SCWE)
- Problem identification and resolution (e.g., the licensee’s corrective action program)

The NRC’s review and assessment of these cross-cutting areas play an important role in the ROP program. A recent change in how cross-cutting issues are assessed and integrated in the program began July 1, 2006 and may be subject to additional changes as more experience is gained.

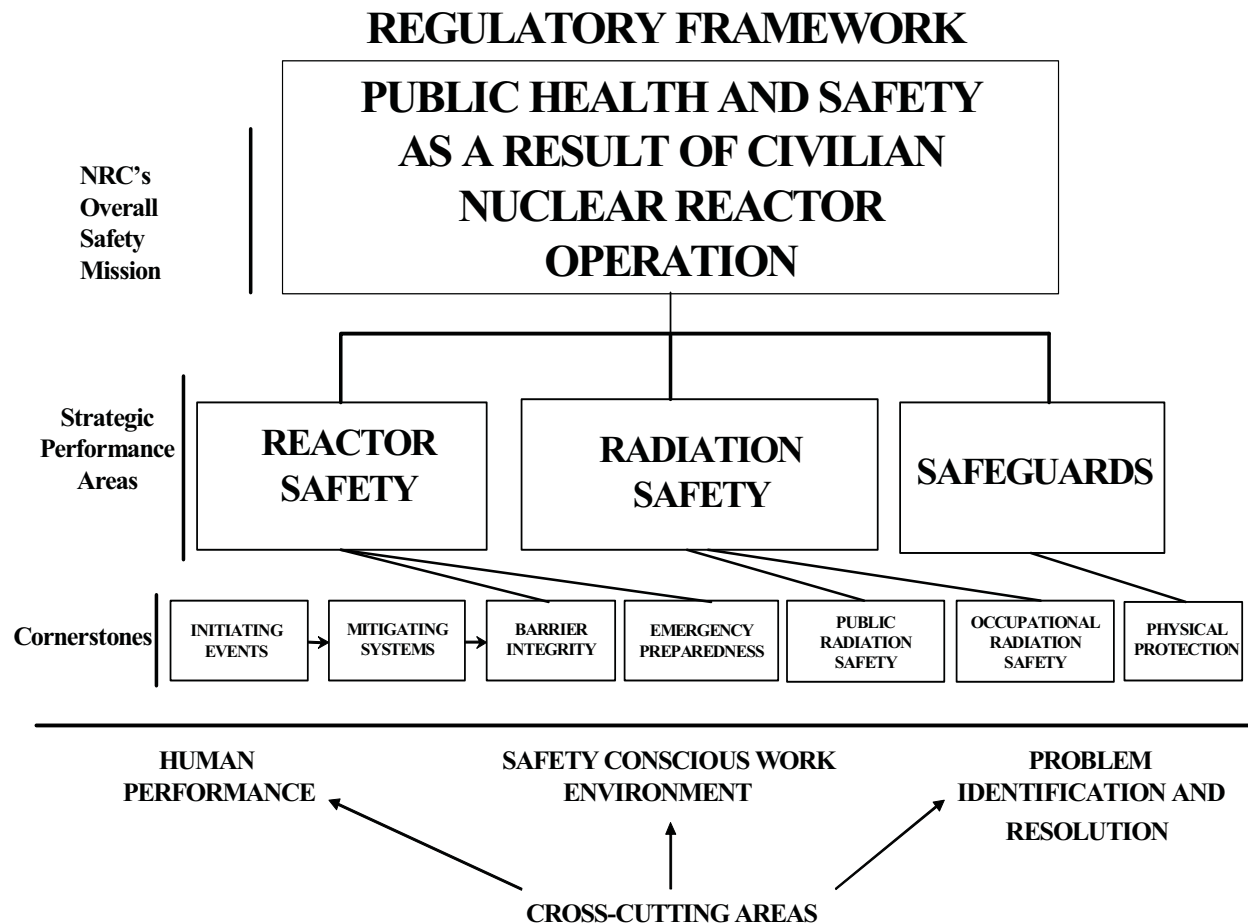


Figure 6.1

Nuclear plant safety performance outcomes are measured by a combination of objective performance indicators (PI) and by the NRC inspection program. PIs use objective data to monitor performance within each of the cornerstones. Licensees generate the data that make up the PIs and submit them to the NRC quarterly. Each PI is measured against established thresholds of performance that are related to their effect on safety. The PIs are evaluated and integrated with the findings of the inspection program.

The ROP includes baseline inspections common to all nuclear plants. These inspections are conducted by resident inspectors (there are at least two resident inspectors at each nuclear power plant site) and by regional and headquarters staff. The baseline inspection program, based on the cornerstone areas, focuses on areas and systems that are risk significant. The baseline inspection program has three parts:

- Inspection in areas not covered by PIs or where a PI does not fully cover inspection area
- Inspections to verify the accuracy of the licensee's reports on performance indicators
- A thorough review of the licensee's effectiveness in finding and resolving problems

Inspections beyond the baseline are performed at plants with performance below established thresholds. Additional inspections may also be performed in response to a specific event or problem at a plant. Special inspections, including those conducted by an Augmented Inspection Team (AIT), are used to review the circumstances surrounding more significant events.

The NRC staff evaluates inspection findings identified during the inspection for safety significance using a significance determination process (SDP). Where possible, the SDP uses quantitative analysis (probabilistic risk analysis) to determine the risk significance. PI data is compared against prescribed risk-informed thresholds. These two distinct items — inspection findings and PIs — are used to conduct the plant assessment. Both aspects of safety performance are evaluated and given a color designation based on their safety significance. Green inspection findings or PIs indicate very low risk significance. White, yellow, or red inspection findings or PIs represent an increasing degree of safety significance.

NRC determines the appropriate level of agency response based on the plant assessment information, which may include supplemental inspection and pertinent regulatory actions ranging from management meetings to orders for plant shutdown. Each plant assessment will fall in to one of the five columns of the NRC action matrix, ranging from performance that only requires baseline inspection and oversight (Licensee Response Column) to unacceptable performance, which may result in an order to modify, suspend or revoke licensed activities:

- Licensee Response Column
- Regulatory Response Column
- Degraded Cornerstone Column
- Multiple/Repetitive Degraded Cornerstone Column
- Unacceptable Performance Column

Enforcement action is taken on safety significant inspection findings, as appropriate. The NRC communicates the results of its performance assessment and its inspection plans and other

planned actions in publicly available correspondence, on its Web site, and through public meetings with each licensee.

In conducting inspections, NRC inspectors follow guidance in the NRC Inspection Manual, which contains objectives and procedures to use for each type of inspection. The Inspection Manual does not contain regulatory requirements and cannot be used to establish any new regulatory requirements or new regulatory guidance.

NRC issues inspection reports to document inspection findings. They may cover a specific time period for the baseline inspection or a particular event or problem examined in a reactive inspection. Inspection reports are intended to be factual and not reflect inspector opinion.

The results of the ROP, including inspection and assessment reports, performance indicators and inspection findings, are posted on the NRC's public Web site, with the exception of security related issues, which are withheld from public access.

6.3 ENFORCEMENT PROGRAM

The purpose of the NRC enforcement program is to support the NRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement actions are used as a deterrent to emphasize the importance of compliance with requirements and to encourage comprehensive correction of violations. NRC's enforcement policy is contained in NUREG-1600, *NRC Enforcement Policy*.

The enforcement policy separates violations associated with inspection findings into two groups, depending on whether the SDP can be used to assess significance. When possible, the SDP is used to evaluate the safety significance of violations. The NRC response to assess the extent of the condition and the adequacy of the corrective actions taken is in accordance with the action matrix. Violations associated with findings evaluated as having very low safety significance (i.e., green) and that are addressed in the licensee's corrective action program are not normally cited. Violations associated with findings evaluated as having a greater significance (i.e., greater than green) are normally cited in a notice of violation (NOV). These violations are not normally subject to civil penalties. In all cases, the licensee must restore compliance with the regulations.

Violations that result in actual consequences, impede the regulatory process, or involve willful acts are processed under the traditional enforcement program since the regulatory importance of these issues is not limited to the underlying technical significance of the findings. These violations are assigned a severity level and licensees are subject to civil penalties in accordance with the criteria described in the NRC enforcement policy. Violations processed under the traditional enforcement program may not receive direct consideration under the action matrix.

Both the traditional enforcement program and the assessment program are exercised for cases in which a violation satisfies the criteria for traditional enforcement and is associated with a finding that has an underlying significance that can be processed under the SDP. Specifically, the violation would be given a severity level and would be considered for a civil penalty. In addition, the significance of the finding would be processed under the SDP and the result would be entered into the action matrix, as appropriate.

7 THE LICENSEE ROLE IN THE REGULATORY PROCESS

7.1 FACILITY DESIGN BASIS AND LICENSING BASIS

The NRC licensee has primary responsibility for operating its plant safely and in compliance with its license. Since a plant's design and operation are not static, certain changes are necessary over the course of the facility's operating life. Reactor licensees must follow NRC regulations to justify and implement changes in the *design basis* and *licensing basis* for their facilities. This section describes the licensee's role in maintaining and updating the licensing basis.

According to 10 CFR 50.2, *design bases* means "that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values chosen for controlling parameters as reference bounds for design."

The *licensing basis* for a plant is comprised of selected information exchanged between a licensee and the NRC relating to design features, equipment descriptions, operating practices, site characteristics, programs and procedures, and other factors that describe a plant's design, construction, maintenance, and operation. Licensing basis information is contained in a variety of document types (e.g., final safety analysis report, license amendments, etc.). Each licensing basis document has certain characteristics in terms of change control mechanisms, reporting of changes to the NRC, dealing with discrepancies, and the possible involvement of the public.

NRC regulations related to license renewal define a facility's *current licensing basis* (CLB) as follows:

"The set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports." (10 CFR 54.3)

7.1.1 Final Safety Analysis Reports and Updated Final Safety Analysis Reports

A final safety analysis report (FSAR) must be included in each application for a license to operate a nuclear reactor facility. The FSAR is intended to describe the facility, present the design bases and the limits on plant operation, and provide a safety analysis of the structures, systems and components (SSC) and of the facility as a whole. Detailed requirements relating to FSAR content are addressed in 10 CFR 50.34(b). The applicant's FSAR is the principal document upon which the NRC bases its safety evaluation supporting the issuance of a facility operating license (OL). The updated FSAR (updated FSAR or UFSAR) incorporates changes made in accordance with 10 CFR 50.71(e). The UFSAR serves as a major source of information on the current plant design and supporting analyses, and is considered part of the current licensing basis.

7.2 **REGULATORY PROCESS CONTROLS USED BY NRC LICENSEES**

Once the NRC issues a license for a nuclear facility, the licensee must operate the facility in compliance with its license. Since a plant's design and operation are not static, certain changes are necessary over the course of its life. Licensees must follow NRC regulations to justify and implement those changes in the design basis and licensing basis. The principal processes, procedures and regulatory vehicles that NRC licensees use in an effort to manage the NRC's licensing and regulatory process are discussed below.

7.2.1 10 CFR 50.59 Reviews (Changes, Tests, and Experiments)

Section 10 CFR 50.59 establishes the framework under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval, and without submitting a license amendment request. A licensee may modify the plant and associated documents (procedures, drawings, updated final safety analysis report, etc.) without prior NRC approval unless the license or technical specifications must be revised to permit implementation of the modification, or the modification meets one or more of the eight criteria specified in 10 CFR 50.59(c)(2). These criteria are:

- (i.) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);
- (ii.) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);
- (iii.) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);
- (iv.) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);
- (v.) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);
- (vi.) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);

- (vii.) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or
- (viii.) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

Plants with general license independent spent fuel Storage installations are also subject to 10 CFR 72.48, *Changes, Tests, and Experiments*. Plants typically add 72.48 to their 50.59 compliance guidance documents because it is a similar, parallel regulation.

7.2.2 License Amendments

Changes to NRC-issued licenses are made through license amendments, and the license amendment process is governed by NRC regulations and regulatory guidance. A reactor operating license may be amended hundreds of times during its term. A licensee must submit a license amendment request (LAR) to the NRC for prior approval if the licensee proposes to modify the license terms and conditions or the technical specifications, or if a proposed change, test or experiment meets the criteria of 10 CFR 50.59(c)(2). It is incumbent upon licensees to provide quality and timely submittals to the NRC to minimize requests for additional information and to avoid unnecessary delays.

LARs are governed by NRC regulations in 10 CFR 50.90-50.92. Procedures and guidance for development and review of license amendments are provided in NRR Office Instruction LIC-101, *License Amendment Review Procedures*.

The applicant (typically the facility licensee) must submit an amendment request in “the form prescribed for original applications,” to the extent applicable, and must “fully describe” the changes required, consistent with the procedural requirements in 10 CFR 50.4. Additionally, Section 50.91(a) requires that LARs for reactor licenses include the licensee’s analysis of the issue of “no significant hazards consideration,” using the requirements in Section 50.92. (This is discussed further below.)

The NRC staff documents its safety analysis of the LAR in a safety evaluation (SE) providing the technical, safety, and legal basis for the NRC’s disposition of the LAR. The SE includes a brief description of the proposed change, the regulatory requirements associated with the change, and an evaluation explaining why the proposed change satisfies the applicable regulatory requirements. The NRC staff also performs an evaluation of the potential environmental consequences of the license amendment and documents its conclusions in an environmental assessment or environmental impact statement. The NRC Atomic Safety and Licensing Board (ASLB) will conduct a hearing on the proposed license amendment in those cases where a hearing request by an individual member of the public or other entity is made and granted. In most instances, the license amendment may be issued before the hearing is held.

Emergency and Exigent License Amendment Requests

In addition to routine LARs, NRC regulations also contemplate the submittal of emergency LARs and exigent LARs. The NRC will generally issue an *emergency license amendment* if the

LAR demonstrates that an “emergency” situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear power plant, or in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level. NRC may issue an *exigent license amendment* if the LAR demonstrates that exigent circumstances exist, in that a licensee and the commission must act quickly and that time does not permit the commission to publish a *Federal Register* notice allowing 30 days for prior public comment. An exigent LAR is generally interpreted as one in which the license amendment is needed in more than seven days but less than four or five weeks. For emergency or exigent license amendment applications, opportunities for public comment on the proposed amendment are typically accelerated or deferred.

“Significant Hazards Consideration” Determinations for LARs

Once the NRC receives an applicant’s LAR for review, it publishes a *Federal Register* notice indicating receipt of the license amendment, either as an individualized notice or as part of a periodic (biweekly) notice of proposed licensing actions indicating each LAR received and each amendment issued. In either case, the *Federal Register* notice for a proposed license amendment will describe the amendment sought, provide the NRC staff’s proposed “significant hazards consideration” determination, and allow a 30-day public comment period on the proposed determination.

The NRC’s determination of “significant hazards considerations” (SHC) is often referred to informally as the “Sholly” process. As noted above, the LAR must include the applicant’s analysis of whether the proposed amendment involves a “significant hazards consideration,” which evaluates whether operation of the facility in accordance with the proposed LAR will: (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

The NRC then performs its own SHC evaluation, using these same criteria. In conducting the SHC evaluation, the NRC is particularly sensitive to an LAR that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a nuclear power plant). The NRC staff may inform the public about the final disposition of a proposed LAR for which it has issued a preliminary “no SHC” determination by issuing an additional *Federal Register* notice. The NRC will not make and will not publish a final determination on the significant hazards consideration issue unless it receives a request for a hearing on the license amendment request.

It should be noted that the “significant hazards consideration” determination is a procedural, rather than substantive, finding by the staff. The SHC determination governs whether a person seeking a hearing on a license amendment is entitled to that hearing before or after the license amendment is issued. The SHC determination is *not* related to the technical licensing determination that the NRC staff makes in connection with the LAR.

During its review of an LAR, the NRC can issue a request for additional information (RAI) to the licensee to further support the technical rationale for the LAR. NRC reviewers are expected

to formulate a single, comprehensive set of questions to elicit pertinent additional information in areas of concern. Multiple rounds of RAIs are to be minimized. In order to achieve this, licensees must ensure that their responses are complete. RAIs and licensees' RAI responses are not to be used to reinterpret regulatory requirements or guidance or produce new regulatory positions. It is also not appropriate for the NRC staff to require or impose commitments unrelated to the requested amendment.

Consolidated Line Item Improvement Process

The Consolidated Line Item Improvement Process (CLIIP) streamlines the NRC review of proposed license amendments that are applicable to multiple plants. Licensees may request license amendments that have been previously assessed and approved by the NRC staff. Regulatory Issue Summary 2000-06, *Consolidated Line Item Improvement Process for Adopting Standard Technical Specifications Changes for Power Reactors*, describes the process by which NRC staff will review a proposed change to technical specifications that is expected to be requested by multiple plant licensees. This standardized process is also described in LIC-101, rev. 3, *License Amendment Review Procedures*. Thus far, the process has been limited to the implementation of NRC-approved changes to the standard technical specifications.

7.2.3 Exemption Requests

An NRC licensee may apply for an exemption from a requirement when it finds that it is not possible or practical to meet some portion of the requirements of a particular rule. Provisions governing a request for exemption by an NRC reactor licensee are found in 10 CFR 50.11 and 50.12. The NRC staff must review exemption requests and will either approve or deny each one. Guidance for development and review of exemption requests are provided in NRR Office Instruction LIC-103, *Requests for Exemption from NRC Regulations*. In essence, the applicant for an exemption must demonstrate that the exemption requested is authorized by law (that is, not otherwise prohibited), will not present an undue risk to public health and safety and is consistent with common defense and security and, most importantly, that "special circumstances" support granting the exemption.

7.2.4 Notices of Enforcement Discretion

An NRC notice of enforcement discretion (NOED) is a regulatory tool for addressing urgent cases in which a noncompliance with technical specifications may require a plant to shut down even though the noncompliance is not associated with a safety concern. The circumstances in which the NRC may exercise enforcement discretion in the form of an NOED are discussed in Part 9900 of the NRC Inspection Manual and in the NRC enforcement policy, Section VII.C.

The issuance of an NOED *does not revise* the licensing bases for a facility. Rather, an NOED acknowledges the noncompliance with the license technical specifications and provides notice to the licensee that enforcement action will not be taken. Significantly, issuance of a NOED does not preclude enforcement action for the underlying conditions that led to the need for the NOED.

NOED requests provide for an expedited NRC review and approval or denial. A verbal approval is typically given prior to issuance of a formally documented safety evaluation. It is the NRC's expectation that NOEDs normally be followed by a license amendment request to formally change the licensing basis as needed. On that point, NRC issued guidance in RIS 2005-01, *Changes to Notice of Enforcement Discretion (NOED) Process and Staff Guidance* (2005), in which it indicated the NRC staff's preference that licensees submit an emergency license amendment instead of a request for enforcement discretion.

7.2.5 Licensee Relief Requests

NRC reactor licensees may submit "relief requests" to the NRC for certain programs that are incorporated into the code of federal regulations by reference. Typically, a relief request may be used when the NRC staff has reviewed and approved certain regulation-mandated programs (e.g. inservice inspection programs) separately from the license. If the licensee subsequently finds that a part of the program has become difficult to perform, for any number of reasons, it may request relief from that portion of the program. The NRC staff must review and approve relief requests by issuing a safety evaluation. As an example, 10 CFR 50.55a specifies the processes for requesting alternatives to, or relief from, the inservice inspection and testing requirements of the ASME Code. Procedures and guidance for development and review of Relief Requests are provided in NRR Office Instruction LIC-102, *Relief Request Reviews*.

7.2.6 Licensee-Initiated Changes to Programs and Plans

A reactor licensee's proposed quality assurance (QA) program, emergency planning/preparedness program, and security plan will be initially approved by the NRC. Subsequent changes to the QA program may be made *without* prior NRC approval, provided that the change does not reduce the commitments made in the program or plan description (10 CFR 50.54(a)). Subsequent changes to the emergency planning/preparedness program and security plan may be made *without* prior NRC approval, provided that the change does not reduce the effectiveness of the program (10 CFR 50.54(q) applies to emergency plans and 10 CFR 50.54(p) applies to the security plan).

7.3 **INDUSTRY DOCUMENTS**

7.3.1 Topical Reports

Vendors, nuclear steam system supplier (NSSS) owners groups and the Electric Power Research Institute submit reports to the NRC for review and approval if a safety assessment is required. Typically, such reports involve component design, analytical models or techniques, operational issues, or performance testing of systems/components. NRC documents its assessment by issuing a safety evaluation (SE). In many cases, individual licensees may submit a license amendment as a pilot application of the topical report or after the NRC SE has been used.

Resolution of issues related to review fees, treatment of proprietary information and intended application by licensees are crucial to efficient and timely review by NRC Staff.

7.3.2 Industry Initiatives and Guidelines

The nuclear industry has historically developed programs and guidelines that have successfully addressed operational, technical and regulatory issues. Such guidelines are strictly voluntary unless they are made a provision in a formal industry initiative.

Formal industry positions (industry initiatives) represent an agreement by each utility chief nuclear officer to undertake a policy level position or implement a specific course of action as a unified industry. Such actions are taken by the Nuclear Energy Institute (NEI) and represent a commitment within the industry. Note, however, that these formal initiatives are not regulatory commitments to the NRC.

Implementation of an industry initiative that involves programs or processes that fall within the scope of 10 CFR 50 may be subject to NRC inspection and enforcement. Guidance documents developed to support implementation of such initiatives may be submitted to NRC for review and endorsement, as appropriate. NRC approval is not typically documented in an SE; rather regulatory guides, generic communications and NRC response letters may be used depending on the issue being addressed.

7.4 **CODES AND STANDARDS**

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) directed federal agencies to use technical standards developed and adopted by voluntary consensus standards bodies. It further directed federal agencies to consult with and participate in voluntary, private sector, consensus standard bodies when such participation is in the public interest and is compatible with the agency mission, priorities and budget. If an agency determines that use of a voluntary consensus standard is inconsistent with applicable law or otherwise impractical, the agency must report to the Office of Management and Budget and provide an explanation. Each federal agency is required to submit an annual report on the nature and extent of participation in the development and use of voluntary consensus standards.

The act also directed the National Institute of Standards and Technology (NIST) to develop a plan for implementing the provisions of the Act dealing with standards conformity. OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment," effective February 19, 1998, was issued to provide policy guidance to federal agencies. This circular defines use as "incorporation of a standard in whole, in part, or by reference in regulation."

This statute and associated guidance was intended to:

- encourage federal agencies to benefit from the private sector
- promote federal agency participation in such bodies to ensure creation of standards that are usable by federal agencies
- reduce reliance on government-unique standards where an existing voluntary standard would suffice

Independent federal agencies were exempted from this law. However, the NRC chose to voluntarily meet the intent of the law. NRC issued Management Directive 6.5, *NRC Participation in the Development and Use of Consensus Standards*, in November 1999. This directive contains organizational responsibilities and guidance for staff participation in the development of consensus standards including identifying and prioritizing needs for new and revised standards; and the use of consensus standards for endorsement including exceptions, and limitations and modifications of standards. The NRC intends to incorporate in the supplementary information for proposed rules or interim final rules statements soliciting comment on NRC intent to use a consensus standard, or its intent to use a government-unique standard with an explanation. Each NRC office has responsibility for implementation and overall coordination is assigned to a standards executive in the Office of Research.

The NRC currently identifies approximately 4,000 codes and standards in regulations, regulatory guides, branch technical positions, the standard review plan, inspection procedures and NUREG documents. According to SECY 99-029, approximately 20 voluntary consensus standards are mandated in NRC regulations. Clearly, a vast number of codes and standards are incorporated into plant design and licensing bases without the need for a regulatory mandate.

8 NRC MANAGEMENT AND CONTROL OF THE REGULATORY PROCESS

Formal mechanisms exist to ensure that NRC conducts its activities in a legal, structured, and disciplined manner in its licensing and oversight of nuclear power plants. These management and control mechanisms include statutes and regulations, commission direction to the staff, backfitting regulations and specific procedures to ensure NRC achieves its legislative mandate and provides “due process” to its licensees.

8.1 LEGISLATIVE

8.1.1 Administrative Procedure Act

As discussed elsewhere in this paper, the Administrative Procedure Act (APA) governs the processes of federal administrative agencies. The original focus of this federal statute was on rulemaking and adjudication. APA requirements can be viewed as functioning as a check or control on the NRC’s licensing and regulatory process in the sense that the APA requires that affected persons be given adequate notice of, and an opportunity to comment on, proposed rules. It provides that, in cases in which another statute requires that the agency provide a hearing on the record, the parties are given adequate opportunity to present facts and argument. It provides interested persons the right to petition an agency for the issuance, amendment, or repeal of a rule, and provides standards for judicial review of agency actions.

The APA now incorporates several other acts that cover a range of processes. Three of these incorporated acts, the Freedom of Information Act, the Government in the Sunshine Act, and the Privacy Act, deal with access to information. The requirement that the NRC must comply with these other statutes may similarly be viewed as a form of control over the way that the agency does business.

8.1.2 Paperwork Reduction Act (OMB clearances)

The Paperwork Reduction Act of 1995 also affects the NRC’s management of its regulatory process, in the sense that this law stipulates that federal agencies justify to the OMB their information collection needs and prepare “industry burden” estimates relating to the proposed collection of information. The OMB has granted generic clearance numbers to be used by NRC program offices when issuing generic communications, so that the NRC is not unduly restricted by having to obtain advance OMB approval for each information request. As a condition for using a generic clearance, NRC staff must ensure that the burden estimate prepared to obtain the generic clearance is accurate.

8.2 COMMISSION DIRECTION

8.2.1 Policy Statements

Policy statements, developed by the NRC staff and approved by the commission, are formal explanations of the NRC's stance on particular issues. As noted in Section 3, NRC may create new or amended substantive rules only by using the "notice and comment" rulemaking process set forth in the APA. However, the APA's requirements for "notice and comment" rulemaking do not apply to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." For the purposes of this paper, it is important to note that the NRC does issue *policy statements*, which (similar to interpretive rules) are exempt under the APA from requirements for notice and comment rulemaking procedure. Thus, NRC statements of policy fall into a different category than legally binding and enforceable regulations.

Policy statements are generally intended to guide the agency staff in the exercise of its discretionary power. The NRC utilizes policy statements both to guide the staff (e.g., the Enforcement Policy) and to establish expectations for licensees (e.g., the Safety Conscious Work Environment Policy). As opposed to an NRC rule, an NRC policy statement does not establish a "binding norm." A policy statement announces the agency's tentative intentions for the future. It leaves the agency and its decision makers free to exercise discretion and does not impose any rights or obligations.

A policy statement, unlike an NRC regulation, is not directly enforceable. Any action to enforce the commission interpretation or policy in a specific case must be by subsequent rule or order issued in accordance with the APA and subject to the NRC's Backfitting Rule, 10 CFR 50.109. However, NRC policy statements do reflect the official views of the commission and, as such, are entitled to considerable deference.

8.2.2 SECY and Staff Requirements Memoranda

Commission papers, known as SECY papers, constitute the principal instrument by which the commission receives information needed for making decisions. They are prepared by the NRC staff and signed by the executive director for operations. The three types of commission papers, affirmation, notation, and information include:

- An affirmation paper requires a commission decision and a commission meeting. Affirmation papers present relatively major policy issues, such as final rules and regulations or proposed commission orders in adjudicatory matters. Commissioners vote through a written notation process and affirm their votes at a public affirmation session.
- A notation paper also requires a commission decision but does not require affirming of commission votes in a public meeting. Similar to an affirmation paper, the commissioners vote through a written notation process on a notation paper.
- An information paper sends to the commission information on significant matters and requires no commission action.

Staff requirements memoranda (SRM) are the commission response to SECYs. After consideration of the issues discussed in a SECY, the NRC commissioners jointly issue an SRM. This SRM may approve, disapprove or modify the NRC staff recommendations in a SECY. SRMs that do not address final rules or orders cannot be used to establish regulatory requirements. However, these commission documents guide the actions of the staff in implementing policy. SRMs and SECYs are not always made publicly available until commission action has been taken.

A commission action memorandum (COM) can come in the form of a SECY. When it is, the document is called a COMSECY. COMSECYs are written exchanges among commissioners about agency issues or NRC staff requests to the commission for guidance.

8.3 BACKFITTING RULE AND CRGR

8.3.1 Backfitting Rule

Backfitting means adding, eliminating or modifying structures, systems or components of a facility after it is licensed. The backfit concept also adds protection from unwarranted, costly, NRC imposed operational and design changes and modifications that would not result in substantial increases in the overall protection of the public health and safety or the common defense and security. In 10 CFR 50.109, backfitting is defined as:

“the modification of or addition to systems, structures, components, or design of a plant or a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a plant or a facility; any of which may result from a new or amended provision in the commission rules or the imposition of a regulatory staff position interpreting the commission rules that is either new or different from a previously applicable staff position after [certain dates].”

The NRC’s backfitting rule relates to the agency actions that impose new or revised staff positions or requirements on licensees. Any changes made under 10 CFR 50.59 at the request of the licensee or voluntarily implemented by the licensee do not constitute backfitting.

Backfitting is a process that can include both plant-specific and generic changes applied to one or more classes of power reactors. There are three types of backfit: compliance, adequate protection, and cost-justified substantial increase in safety.

The NRC staff is responsible for evaluating all proposed new or revised staff positions to determine whether the positions are backfits, and for identifying facility-specific and generic backfits.

A backfitting analysis is not required when ensuring compliance with the existing regulatory requirements or written licensee commitments. For compliance backfits, the staff need not consider the costs. It is not permissible for the NRC to redefine what constitutes compliance and then apply the compliance backfit aspect of the regulation to avoid a proper backfit analysis. Such redefinition of what is compliance is itself a backfit and must be analyzed per the

regulation before the new definition is implemented. A backfitting analysis is also not required if imposition of a backfit is necessary to ensure that the facility provides adequate protection to the public health and safety or common defense and security.

For all the backfits other than compliance or adequate protection exceptions, the NRC staff must perform a backfit analysis. Additionally, the NRC staff may also be required to prepare a regulatory analysis to show that certain improvements in safety or security are justified on the basis of the associated costs balanced against the improvement in plant safety.

Information and procedures for backfitting are found in: LIC-400, *Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees*; MD 8.4, *Management of Plant-Specific Backfitting of Nuclear Power Plants*; and LIC-202, *Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests*

8.3.2 Committee to Review Generic Requirements

The Committee to Review Generic Requirements (CRGR) consists of NRC senior managers from the Offices of the General Counsel (OGC), Nuclear Regulatory Research (RES), Nuclear Reactor Regulation (NRR), Nuclear Materials Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), and one of the regional offices on a rotational basis. The CRGR reports to the executive director for operations (EDO), who appoints the committee chair and members. The CRGR conducts its activities in accordance with the committee's charter Revision 7, dated November 7, 1999, which describes the committee's mission, scope of activities, and operating procedures. RES provides technical and administrative support to the committee.

The CRGR's mission is to ensure that new or revised generic requirements proposed by the NRC staff to impose on licensed power reactor and nuclear materials licensees are appropriately justified based on the backfit provisions of the applicable NRC regulations and the commission's backfit guidance and pertinent policy. Revision 4 of NUREG/BR-0058, *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, dated July 2004, provides guidance relevant to the required regulatory analysis.

The primary responsibilities of the CRGR are to recommend to the EDO either approval or disapproval of the staff's proposed generic actions and to assist the NRC program offices in ensuring consistency with the implementation of the commission's regulations, directives and guidance.

To accomplish its mission, the CRGR reviews proposed new or revised regulatory requirements related to nuclear power reactors; NUREG-series reports; safety evaluation reports (SERs) that endorse generic vendor initiatives; generic communications, such as information requests pursuant to 10 CFR 50.54(f); regulatory guides; and NRC staff guidance on licensing, inspection, assessment and enforcement, which could imply or inadvertently impose an unjustified backfit. The CRGR reviews selected nuclear materials issues and proposed new or revised nuclear materials-related requirements, generic communications and regulatory guidance. In addition, the CRGR holds periodic meetings with stakeholders as part of its responsibility for monitoring

the overall effectiveness of NRC's generic backfit management process. As part of its responsibility for regulatory effectiveness, the CRGR may conduct periodic audits of NRC's administrative controls for facility-specific backfitting to assess their effectiveness.

8.4 MANAGEMENT DIRECTIVES AND NRR OFFICE INSTRUCTIONS

In addition to the technical guidance to the staff discussed in Section 4, NRC also issues management directives and NRR office instructions to manage and control the regulatory process. Management directives specify policy, objectives, responsibilities, and authorities in specific functional areas. They guide, inform, and instruct NRC employees in the performance of their jobs and communicate policies to enable employees to work effectively within the agency, with other agencies, and with the public.

NRR has established a set of procedures and guidance for its staff to meet the requirements and performance goals established in legislation, regulations, the agency's strategic plan, and office-level operating plans. They are typically issued to address (1) significant, repetitive activities that include responsibilities for two or more NRR divisions (e.g., licensing actions), or (2) important activities or responsibilities that are not adequately addressed by higher level guidance.

A partial list of management directives and NRR office instructions that address various topics discussed in this white paper is included in the appendix. Neither management directives nor office instructions can revise, modify or interpret regulatory requirements.

APPENDIX: REFERENCED NRC MANAGEMENT DIRECTIVES AND OFFICE INSTRUCTIONS

Relevant Management Directives

MD 6.3, *The Rulemaking Process*: When developing rulemaking actions several activities must be performed. Offices must coordinate together and ensure that staff resources are used efficiently. Schedules for rulemaking actions must be met and Agreement States must be provided an opportunity for comments. The public and stakeholders must have the maximum opportunity to participate in proceedings. MD 6.3 provides guidance for all of the above issues and documents the proper method for initiation, planning and approval or denial of a final rule.

MD 6.5, *NRC Participation in the Development and Use of Consensus Standards*: Organizational responsibilities and guidance are provided for (1) staff participation in the development of consensus standards, including identifying and prioritizing needed new and revised technical standards, selecting and nominating staff as authorized agency representatives on standards developing organization (SDO) committees, and coordinating standards activities with SDOs and other stakeholders, and (2) NRC use of consensus standards including identifying and prioritizing standards for endorsement, timely endorsement, annual reporting, exceptions to using a consensus standard, and monitoring and assessing the NRC standards program.

MD 8.4, *Management of Plant-Specific Backfitting of Nuclear Power Plants*: The purpose of this directive is to ensure that backfitting of a nuclear power reactor or materials facility is appropriately justified and documented and that the executive director for operations is responsible for ensuring proper implementation of the backfit process and that the NRC is not unnecessarily burdened. This directive is also intended to ensure that NRC-licensed facilities provide adequate protection of public health and safety and common defense and security.

MD 8.13, *Reactor Oversight Process*: The reactor oversight process (ROP) is necessary to obtain information about operations at reactor facilities, identify significant safety concerns and determine the causes of declining performance. Assessment of performance must be communicated effectively to both internal and external stakeholders. MD 8.13 is used to evaluate the risk significance of issues to ensure that all parties involved respond appropriately. Regulatory responses are measured and provided on the basis of safety significance.

Relevant NRR Office Instructions

COM-203, *Informal Interfacing and Exchange of Information with Licensees and Applicants*: The objective of this office instruction is to provide guidance for interfacing with licensees and applicants in less formal circumstances, and for documenting such interfaces. It applies to licensing actions associated with operating reactors, license renewal and new reactor license applications. The guidance applies to informal meetings and discussions, phone calls, e-mails, facsimiles, exchange or review of draft information, and receipt of unsolicited information.

LIC-100, *Control of Licensing Bases for Operating Reactors*: This office instruction provides NRR staff with the basic framework for making decisions about creating, revising or deleting licensing bases information for operating power reactors. These procedures are intended to enhance NRR's efficiency in responding to the needs of both the licensees and the public. Specific objectives include the following: (1) ensure the effective use of NRC's regulatory processes maintains the public health and safety, (2) promote public confidence in NRC licensing processes by establishing a common reference, an understandable framework for licensing bases decisions, and a common understanding of roles, responsibilities and opportunities for participation, (3) reduce unnecessary regulatory burdens by establishing a common understanding of the control of licensing bases and by promoting the use of the most appropriate licensing process to achieve the desired results, and (4) increase the effectiveness, efficiency, and realism of nuclear licensing by establishing a common reference for processes, communications, and decisionmaking.

LIC-101, *License Amendment Review Procedures*: This document provides NRR staff with the basic framework for processing license amendment (and other licensing actions, where applicable) applications. The goal is to: (1) ensure the public health and safety are maintained, (2) promote consistency in processing of license amendments, (3) improve internal and external communications, (4) increase technical consistency for similar licensing actions, (5) reduce delays in the issuance of license amendments (meet licensing action timeliness goals) of 96 percent less than 1 year old and 100 percent less than 2 years old), and (6) ensure that staff RAIs are adding value to the regulatory process.

LIC-102, *Relief Request Reviews*: The objective of this office instruction is to give guidance for handling licensee's relief requests submitted in accordance with 10 CFR 50.55a. Guidance is provided on methods to permit a licensee to deviate from regulatory requirements related to codes and standards, as well as guidance on the content of the safety evaluations and cover letters authorizing alternatives, granting relief or approving later code editions and addenda pursuant to various 10 CFR 50.55a paragraphs.

LIC-103, *Requests for Exemption from NRC Regulations*: This office instruction provides NRR staff members with a basic framework for processing requests for exemptions submitted under Sections 20.2301, 40.14, 50.12, 51.6, 52.93(a), 54.15, 55.11, and 70.17, and exemptions granted by the commission on its own initiative. These procedures are intended to enhance NRR's efficiency in responding to the needs of licensees and the public. The document is intended to promote consistency in the processing of exemption requests by giving the NRR staff an improved framework for processing them.

LIC-105, *Managing Regulatory Commitments Made by Licensees to the NRC*: This document provides NRR staff with guidance on managing regulatory commitments. The guidance is consistent with available industry guidance and is intended to ensure common understanding (by the staff, licensees, and other agency stakeholders) of the handling of regulatory commitments. With this office instruction, the NRC aims to reduce unnecessary regulatory burden by establishing a common understanding of the control of regulatory commitments and by promoting the use of regulatory commitments when it is appropriate to achieve the desired results. In addition, the document is expected to increase the effectiveness and efficiency of the

licensing process by establishing a common reference for processes, communications, and decision making involving regulatory commitments.

LIC-106, *Issuance of Safety Order*: This office instruction is intended to provide the NRR staff guidance on the process, preparation and issuance of safety orders and ensure that the NRR staff performs the appropriate regulatory and technical reviews of information in support of proposed safety orders. The scope of this office instruction is limited to orders that impose additional regulatory requirements and actions beyond the current regulatory framework, i.e., license modification orders, referred to as safety orders. Compliance orders that enforce compliance within the existing regulatory framework are not addressed in this office instruction. Orders that include both compliance issues and safety issues shall be processed in the same manner as compliance orders. Process procedures for compliance orders are delineated in the enforcement manual.

LIC-200, *Standard Review Plan (SRP) Process*: This instruction provides guidance for using the SRP in review of license and design certification applications under 10 CFR Part 50 and Part 52. LIC-200 also provides guidance for identifying and reviewing operational programs in combined license applications. Future guidance will be available to aid the NRC staff in the review and inspection of systems, structures, and components in accordance with risk-significant determinations.

LIC-202, *Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests*: The backfit rule is detailed in 10 CFR 50.109. The backfit rule enables the NRC staff to research information necessary to determine if a plant's license must be modified, revoked or suspended. This instruction ensures that any backfitting by the NRC is properly justified and documented. Responsibilities of the NRR staff are also detailed in the instruction. LIC-202 should be used in conjunction with LIC-100.

LIC-300, *Rulemaking Procedures*: The NRC must develop rules that are consistent with the requirements of all applicable laws and regulations. This office instruction establishes procedures for conducting rulemaking activities. The LIC-300 rulemaking process establishes responsibilities for initiating, developing and reviewing rulemaking packages. The process also includes obtaining input, review and concurrence from other NRC offices.

LIC-400, *Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees*: The NRC must have an effective program for controlling the development and revision of generic requirements imposed on power reactor licensees. This office instruction details the responsibilities of the Committee to Review Generic Requirements (CRGR). The CRGR charter was developed for generic backfits. The CRGR is responsible for reviewing and approving all new generic requirements developed after November 12, 1981. The CRGR also reviews selected requirements and staff positions.

LIC-500, Revision 3, *Processing Requests for Reviews of Topical Reports*: This describes the process by which NRR staff and managers process topical reports and thereby improve NRR's efficiency and consistency. It contains guidance on review fees, treatment of proprietary information and plant-specific licensing actions.

LIC-503, Revision 2, *Generic Communications Affecting Nuclear Reactor Licensees*: This office instruction provides criteria for using generic communications (bulletins, generic letters, regulatory issue summaries and information notices) to address generic concerns. Generic issues evolve from nuclear reactor operating experience and regulatory initiatives and have broad applicability. LIC-503 also provides guidance and procedures for generic issue preparation, distribution, follow-up and closeout.

OVRST-101, *Procedures for Tracking Inspection Reports for Inspections Conducted by NRR Headquarters Staff*: This office instruction primarily supports the requirements established by Public Law 101-508 that the NRC should assess fees to recover funds appropriated by Congress for each fiscal year. This office instruction provides procedures and instructions for NRR inspectors to obtain inspection report numbers. Inspection report numbers are used for tracking staff hours and/or contractual costs associated with NRR inspection efforts, and for recording the time expended to issue an inspection report.